IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NIPPON SHINYAKU, LTD., Plaintiff, v. SAREPTA THERAPEUTICS, INC., Defendant.	C.A. No. 21-1015-GBW **REDACTED PUBLIC VERSION**
SAREPTA THERAPEUTICS, INC. and UNIVERSITY OF WESTERN AUSTRALIA, Defendant/Counter-Plaintiff, v. NIPPON SHINYAKU CO., LTD. and NS PHARMA, INC., Plaintiff/Counter-Defendants.	

MEMORANDUM OPINION AND SPECIAL MASTER ORDER #2

Before the Special Master are three discovery disputes between Nippon Shinyaku, Ltd. and NS Pharma, Inc. (collectively, "Nippon Shinyaku") and Sarepta Therapeutics, Inc. ("Sarepta") and University of Western Australia ("UWA"). The table below lists the three disputes and the movant for each.

DISPUTES	MOVANT
1. Motion to compel Sarepta to produce license agreements relating to Duchenne Muscular Dystrophy therapies beyond solely exon-skipping therapies and to produce an unredacted version of the Roche Agreement	Nippon Shinyaku
2. Motion to compel Nippon Shinyaku to produce inventor Dr. Takeda for deposition in the United States	Sarepta
3. Motion to compel Sarepta and UWA to produce inventors Drs. Fletcher and McClorey for deposition	Nippon Shinyaku

On June 15, 2023, each party submitted motions for the disputes where it is the movant. D.I. 246, 247. The parties also submitted letter briefing on each of the motions, and the Special Master held a transcribed videoconference hearing on June 21, 2023. D.I. 226. This Memorandum Opinion and Order addresses the parties' motions.

Having considered the letter briefs and arguments presented by the parties, for the reasons set forth below, IT IS HEREBY ORDERED that: (1) Nippon Shinyaku's motion to compel Sarepta to produce license agreements relating to Duchenne Muscular Dystrophy ("DMD") therapies beyond solely exon-skipping therapies and to produce an unredacted version of the Roche Agreement is **DENIED IN PART** and **GRANTED IN PART** (D.I. 247); (2) Sarepta's motion to compel Nippon Shinyaku to produce inventor Dr. Takeda for deposition in the United States is **GRANTED** (D.I. 246); and (3) Nippon Shinyaku's motion to compel Sarepta and UWA to produce inventors Drs. Fletcher and McClorey for deposition is **DENIED** (D.I. 247).

I. BACKGROUND

This case involves the parties' cross-assertions of patent infringement. Nippon Shinyaku asserts infringement of seven patents (the "NS Patents") against Sarepta, and Sarepta and UWA assert infringement of three patents (the "UWA Patents") against Nippon Shinyaku. All of the patents-in-suit relate to exon-skipping antisense oligomer ("ASO") products offered for sale in the United States for the treatment of DMD.

Nippon Shinyaku and National Center of Neurology and Psychiatry ("NCNP") are assignees of the NS patents. The named inventors on the NS patents are Naoki Watanabe, Youhei Satou, Shin'ichi Takeda, and Tetsuya Nagata. Nippon Shinyaku holds the exclusive assertion rights for the NS Patents by way of a license agreement it has with NCNP. NCNP is not a party in this case.

UWA is the assignee of the UWA Patents. The named inventors on the UWA Patents are Stephen Donald Wilton, Sue Fletcher, and Graham McClorey. Sarepta has exclusive rights to the UWA Patents for the treatment of DMD and the right to enforce the UWA Patents.

II. LEGAL STANDARD

Pursuant to Rule 26 of the Federal Rules of Civil Procedure: "[p]arties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense and proportional to the needs of the case, considering the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit. Information within this scope of discovery need not be admissible in evidence to be discoverable." Fed. R. Civ. P. 26(b)(1).

"Generally, a party moving to compel bears the burden of demonstrating the relevance of the requested information." *Delaware Display Group LLC v. Lenovo Group Ltd.*, No. 13-2018-RGA, 2016 WL 720977, at *2 (D. Del. Feb. 23, 2016).

III. DISCUSSION

A. Nippon Shinyaku's Motion to Compel Sarepta to Produce License Agreements Relating to DMD therapies Beyond Solely Exon-Skipping Therapies and to Compel Sarepta to Produce an Unredacted Version of the Roche Agreement (Dispute 1)

Nippon Shinyaku moves to compel Sarepta to produce license agreements relating to all of Sarepta's AON and DMD therapies beyond solely exon-skipping therapies, and to compel Sarepta to produce an unredacted version of an agreement between Sarepta and Roche (the "Roche Agreement"). D.I. 247; Nippon Shinyaku's Opening Brief at 1, 2, 4. Nippon Shinyaku argues that license agreements relating to all of Sarepta's AON and DMD therapies are discoverable and

should be produced because they are relevant to the parties' damages analysis, namely, the reasonable royalty analysis. *Id.* at 2. Nippon Shinyaku argues that the license agreements it seeks are relevant to "[t]he rates paid by the licensee for the use of other patents comparable to the patent in suit" and, therefore should be produced during discovery. *See Georgia-Pacific Corp. v. United States Plywood Corp.*, 318 F. Supp. 112 (S.D.N.Y. 1970) (discussing *Georgia-Pacific* Factor 2). *Id.* at 2.

Nippon Shinyaku also argues that the license agreements for all of Sarepta's AON and DMD therapies are relevant because of "the importance of understanding the relative value of technologies used in the treatment of DMD." *Id.* at 2. According to Nippon Shinyaku, all such documents are relevant to this case and should be produced because the patient populations for Sarepta's various commercial and developmental products and therapies for treating DMD "overlap" and "the relative economic value of each product is inextricably tied to the others." *Id.* at 2.

Regarding the Roche Agreement, Nippon Shinyaku argues that Sarepta should be compelled to produce an unredacted version because the agreement appears to grant Roche "certain rights relating to Vyondys53®" (a Sarepta product accused of infringement in this case) and "other DMD therapies." Nippon Shinyaku's Opening Brief at 3. Although Sarepta has produced a redacted version of the Roche Agreement, Nippon Shinyaku contends that Sarepta's redactions are improper because they impair Nippon Shinyaku's "ability to analyze key aspects of the overall bargain struck between Sarepta and Roche . . . and relevant information regarding current and future DMD products that affect the market for both accused products in this case." *Id.* at 3.

In response, Sarepta argues that Nippon Shinyaku's motion should be denied because it improperly seeks information that is "irrelevant to the claims and defenses of this action" and "goes far beyond the proportionality standard that Rule 26 requires." Sarepta's Opening Brief at 1. Sarepta argues that Nippon's Shinyaku's demand for documents is overbroad and not proportional to the needs of this case because it seeks ***all*** of Sarepta's agreements and licenses relating to ***all*** AON and DMD therapies regardless of whether they are exon-skipping therapies. *Id.* at 1. Sarepta also argues that Nippon Shinyaku seeks to obtain sensitive commercial information from Sarepta, a direct competitor, involving different patents and products than those relevant and at issue in this case. *Id.* at 1, 3. Sarepta maintains that it has already produced relevant exon-skipping licenses and agreements commensurate with the scope of the claims and defenses in this case and the parties' prior negotiations on this issue. *Id.* at 3.

Regarding the Roche Agreement, Sarepta argues that Nippon Shinyaku is not entitled to an unredacted version of that agreement because it is not a license. Sarepta's Opening Brief at 3.

[redacted]

Nippon Shinyaku's motion is **DENIED** to the extent that it seeks to compel Sarepta to produce: (1) ***all*** agreements and licenses relating to ***all*** DMD therapies, regardless of whether they target exon 53 or are exon-skipping therapies, and (2) ***all*** of Sarepta's licenses relating to nucleic acid-based therapies known as AONs regardless of whether they skip exons or treat DMD. Nippon Shinyaku's demand for all such documents is overbroad and not proportional to the needs of this case because it is not commensurate with the scope of the claims and defenses in the case and the parties' prior negotiations on this issue. It is undisputed that the patents-in-suit all relate to

exon-skipping ASO products offered for sale in the United States for the treatment of DMD, and specifically to exon-skipping therapies targeting exon 53. Yet, Nippon Shinyaku's motion seeks the production of ***all*** licenses and agreements for ***all*** of Sarepta's AON and DMD therapies regardless of whether they target exon 53 or are exon-skipping therapies. It is also undisputed that in prior correspondence with Sarepta regarding this dispute, Nippon Shinyaku confirmed that the scope of the dispute was "[a]ll agreements/licenses related to developing exon-skipping oligonucleotides and/or Vyondys53® . . . ," which is much narrower than the broad scope of discovery Nippon Shinyaku now seeks in its motion.

The Special Master is not persuaded that the broad scope of documents that Nippon Shinyaku seeks is relevant or that all such documents are even potentially comparable to the patents-in-suit. Although Nippon Shinyaku argues that license agreements relating to all of Sarepta's AON and DMD therapies are relevant to the reasonable royalty analysis, i.e., *Georgia-Pacific* factor 2, Nippon Shinyaku does not meaningfully explain how or why all such documents, particularly those unrelated to exon-skipping or DMD treatment therapies, are relevant or otherwise comparable to any of the asserted patents. Nippon Shinyaku's assertions that the requested documents are relevant to "understanding the relative value of technologies used in the treatment of DMD" and that "the relative economic value of each product is inextricably tied to the others" are speculative and, without more, insufficient to satisfy Nippon Shinyaku's burden in this regard.

Nippon Shinyaku's motion is **GRANTED IN PART** to the extent that it seeks to compel Sarepta to produce an unredacted version of the Roche Agreement, subject to the Special Master's *in camera* review of the unredacted Roche Agreement to assess the scope of Sarepta's redactions and facilitate appropriate redactions, as necessary. The Special Master is persuaded, and Sarepta

essentially admits, that at least certain portions of the Roche Agreement are relevant to the accused Vyondys53® product, and therefore, that the Roche Agreement should be produced, at least in part and with appropriate redactions following *in camera* review by the Special Master.

Accordingly, Nippon Shinyaku's motion to compel Sarepta to produce license agreements relating to all of Sarepta's AON and DMD therapies beyond solely exon-skipping therapies, and to compel Sarepta to produce an unredacted version of the Roche Agreement is **DENIED IN PART** and **GRANTED IN PART**.

IT IS FURTHER HEREBY ORDERED that within two (2) business days of this Memorandum Opinion and Order, Sarepta shall provide by email only to the Special Master and not to Nippon Shinyaku, a pdf copy of the full, unredacted version of the Roche Agreement, along with a pdf copy of the redacted version of the Roche Agreement that Sarepta has produced in this case. The Special Master will review the documents *in camera* and thereafter provide further guidance regarding scope of Sarepta's redactions.

B. Sarepta's Motion to Compel Nippon Shinyaku to Produce Inventor Dr. Shin'ichi Takeda for Deposition in the United States (Dispute 2)

Sarepta moves to compel Nippon Shinyaku to produce Dr. Takeda for deposition in the United States. D.I. 246; Sarepta's Opening Brief at 1. Dr. Takeda is one of the named inventors on the NS Patents and a current employee of NCNP in Japan. *Id.* at 1. Sarepta argues that Nippon Shinyaku should produce Dr. Takeda for deposition in the United States because Dr. Takeda possesses relevant, unique, and discoverable information regarding the claimed subject matter of the NS Patents asserted in this case. *Id.* at 1. Sarepta also argues that Dr. Takeda executed an assignment agreement (the "Assignment Agreement") that granted his interest in the NS Patents

to Nippon Shinyaku and NCNP and obligates him to testify in the United States in patent infringement actions concerning enforcement of the NS Patents. *Id.* at 1.

Sarepta contends that Dr. Takeda's Assignment Agreement, in relevant part, states:

> AND I/WE HEREBY further covenant and agree that I/WE will, without further consideration, communicate with assignee . . . any facts known to ME/US respecting this invention and testify in any legal proceeding, . . . and generally do everything possible to aid assignee . . . to obtain and enforce proper patent protection for this invention in the United States . . . .

Sarepta's Opening Brief at 1. Sarepta also contends that, in addition to the language in Dr. Takeda's Assignment Agreement, both NCNP and Nippon Shinyaku entered a subsequent litigation agreement that grants Nippon Shinyaku the "exclusive right to pursue infringements of the NS Patents" and requires NCNP to "provide its full cooperation to a reasonable extent, in accordance with the requests by" Nippon Shinyaku. *Id.* at 1.

Sarepta argues that, because courts have found nearly identical assignment agreement language to require the patentee to produce foreign inventors for deposition in the United States, Nippon Shinyaku should be compelled to produce Dr. Takeda for deposition in the United States. *Id.* at 3 (citing *Aerocrine AB v. Apieron Inc.*, 267 F.R.D. 105, 111-12 (D. Del. 2010)).

In response, Nippon Shinyaku argues that Sarepta's motion to compel a deposition of Dr. Takeda in the United States should be denied because Sarepta "fails to give due consideration to the factors governing the proportionality of such a deposition to the needs of this case and fails to provide any justification for why a remote deposition will not be sufficient." Nippon Shinyaku's Response Brief at 1. Nippon Shinyaku argues that Sarepta's demand to depose Dr. Takeda in the United States is not justified because Nippon Shinyaku is already providing four other witnesses for deposition in the United States who it expects to testify about Nippon Shinyaku's research and collaboration with NCNP. *Id.* at 1.

Nippon Shinyaku also argues that Sarepta's demand to depose Dr. Takeda in the United States is disproportionate to the needs of this case because Sarepta offers no argument to justify why an in-person deposition in the United States would be necessary and Nippon Shinyaku is not withholding discovery regarding Dr. Takeda's and NCNP's involvement in the research leading to the NS Patents. *Id.* at 3. Nippon Shinyaku maintains that a deposition of Dr. Takeda would be "highly burdensome, particularly if not located in Japan or conducted remotely." *Id.* at 4.

Sarepta's motion to compel Nippon Shinyaku to produce Dr. Takeda for deposition in the United States is **GRANTED**. In view of the facts of this case, the Special Master is persuaded that the weight of the applicable case law supports Sarepta's position. The Special Master finds the facts and analysis in the *Aerocrine* case that Sarepta cites in its opening letter brief particularly instructive. Similar to the facts in *Aerocrine*, Dr. Takeda is a co-inventor on the asserted NS Patents and possesses knowledge relevant to the claimed subject matter of the asserted patents. Dr. Takeda is also an employee of NCNP and a party to the Assignment Agreement with Nippon Shinyaku and NCNP for the NS Patents that specifically contemplates and expressly requires Dr. Takeda to "testify in any legal proceeding, and generally do everything possible to aid assignee . . . to obtain and enforce proper patent protection for this invention in the United States." *See Aerocrine*, 267 F.R.D. at 111-12 (finding co-inventors similarly obligated under an assignment agreement "to testify in any judicial proceeding . . . and do everything possible to aid [assignee] to obtain and enforce said letter Patent in the United States when requested to do so by the [assignee]"). In addition to the express language in Dr. Takeda's Assignment Agreement, there is no dispute that the subsequent litigation agreement entered between Nippon Shinyaku and NCNP requires NCNP to "provide its full cooperation to a reasonable extent, in accordance with the requests by" Nippon Shinyaku.

Thus, for purposes of providing deposition testimony in this case, the Special Master is persuaded that Nippon Shinyaku has control of Dr. Takeda and is therefore obligated to produce Dr. Takeda for deposition in the United States.

Nippon Shinyaku's arguments that an in-person deposition of Dr. Takeda in the United States is not justified, and that it would be highly burdensome if the deposition is not located in Japan or conducted remotely are not well taken because Nippon Shinyaku has not provided any evidence to support them. Nippon Shinyaku does not, for example, identify any financial hardship or inability by Dr. Takeda to attend a deposition in the United States. Although during the June 21, 2023 Hearing, counsel for Nippon Shinyaku stated that "it is unlikely that [counsel] could get Dr. Takeda and arrange for him to travel to the United States before [August 14, 2023]" and that it was "going to be very difficult, given his schedule," counsel did not state that Dr. Takeda would be unable to attend a deposition in the United States "if the Court orders [counsel] to make him available sooner." *See* June 21, 2023 Hrg. Tr. at 36:23-37:1, 37:16-21.

Accordingly, Sarepta's motion to compel Nippon Shinyaku to produce Dr. Takeda for deposition in the United States is **GRANTED**.

IT IS FURTHER HEREBY ORDERED that Nippon Shinyaku shall make Dr. Shin'ichi Takeda available for deposition in the United States at a mutually agreeable date, time, and location within twenty-five (25) days of this Memorandum Opinion and Order.

C. Nippon Shinyaku's Motion to Compel Sarepta and UWA to Produce Inventors Drs. Fletcher and McClorey for Deposition (Dispute 3)

Nippon Shinyaku moves to compel Sarepta and UWA to make at least one of Dr. Sue Fletcher and Dr. Graham McClorey available for deposition. D.I. 247; Nippon Shinyaku's Opening Brief at 1. Dr. Fletcher and Dr. McClorey are two of the named co-inventors on the UWA

Patents and both former employees of UWA. *Id.* at 1. They also both reside outside of the United States. *Id.* at 1. Nippon Shinyaku argues that Sarepta and UWA should be compelled to produce Drs. Fletcher and McClorey for deposition in this case "as a matter of fairness and proportionality." *Id.* at 5. In particular, Nippon Shinyaku argues that

> the Court compel equal numbers of inventor depositions—*i.e.*, [Nippon Shinyaku's] choice of deposing either Dr. Fletcher or Dr. McClorey should the Court deny Sarepta's and UWA's motion regarding [Discovery] Issue #2, and depositions for both Dr. Fletcher and Dr. McClorey should the Court grant that motion.

Nippon Shinyaku's Opening Brief at 5. Nippon Shinyaku contends it "has a *need* to depose at least one of Dr. Fletcher and/or Dr. McClorey to understand what each of their purported contributions to the claimed exon-53 skipping oligonucleotides were." *Id.* at 6.

Nippon Shinyaku argues that the Court has authority to order at least UWA to produce Dr. Fletcher and/or Dr. McClorey because Drs. Fletcher and McClorey both assigned their patent rights to the UWA Patents to UWA in an assignment agreement (the "UWA Assignment Agreement"). *Id.* at 7. Nippon Shinyaku contends that the UWA Assignment Agreement, in relevant part, states:

> to issue all letters patent on said invention to ASSIGNEE. ASSIGNORS agree to execute all instruments and documents required for the making and prosecution of applications for United States and foreign letters patent on said invention, for litigation regarding letters patent, or for the purpose of protecting title to said invention or letters patent therefore.

Id. at 7. Nippon Shinyaku argues that this language in the UWA Assignment Agreement is akin to language in assignment agreements that courts in the District of Delaware have found to obligate production of foreign inventors for deposition. *Id.* at 7 (citing *Amgen, Inc. v. Ariad Pharms., Inc.*, No. 06-cv-259-MPT, 2007 WL 1425854, at *2 (D. Del. May 14, 2007) and *Aerocrine AB v. Apieron Inc.*, 267 F.R.D. 105, 111-12 (D. Del. 2010)).

In response, Sarepta and UWA argue that Nippon Shinyaku's motion should be denied because neither Sarepta nor UWA has control over Drs. Fletcher and McClorey to compel them to appear at a deposition. Sarepta's Responsive Brief at 4. Rather, Sarepta and UWA contend that Drs. Fletcher and McClorey are not current employees of either Sarepta or UWA, and that they are both foreign residents: Dr. Fletcher, a resident of Australia and Dr. McClorey, a resident of the U.K. *Id.* at 4. Sarepta and UWA also contend that Drs. Fletcher and McClorey do not have contractual obligations to testify and that the UWA Assignment Agreement they executed transferring patent rights to UWA does not even mention testifying. *Id.* at 4. Instead, Sarepta and UWA maintain that the UWA Assignment Agreement only obligates Drs. Fletcher and McClorey to sign documents. *Id.* at 4.

Nippon Shinyaku's motion to compel Sarepta and UWA to produce inventors Drs. Fletcher and McClorey for deposition is **DENIED**. Neither Sarepta nor UWA has control of Drs. Fletcher and McClorey to compel them to appear at a deposition. Drs. Fletcher and McClorey are also not current employees of Sarepta or UWA, and the UWA Assignment Agreement they executed does not contain any specific language obligating them to testify in any legal proceeding or appear for a deposition. Rather, as Sarepta and UWA correctly point out, all that the UWA Assignment Agreement obligates Drs. Fletcher and McClorey to do is sign documents. The UWA Assignment Agreement merely states that "ASSIGNORS agree to execute all instruments and documents required . . . for litigation regarding letters patent, or for the purpose of protecting title to said invention or letters patent therefore." Sarepta's Responsive Brief at 5.

Nippon Shinyaku's reliance on the *Aerocrine* case is misplaced. In contrast to the assignment agreement in *Aerocrine* and Dr. Takeda's Assignment Agreement discussed above in connection with Dispute 2, the UWA Assignment Agreement does not include specific language

that requires Drs. Fletcher and McClorey "***to testify in any legal proceeding***" regarding the UWA Patents. *See Aerocrine*, 267 F.R.D. at 111-12 (emphasis added).

Nippon Shinyaku's reliance on the *Amgen* case is also misplaced. In contrast to the UWA Assignment Agreement, the assignment agreement in *Amgen* required inventors "to perform any other lawful acts which may be deemed necessary to secure fully the aforesaid invention," including "***the giving of testimony in any interference or other proceeding*** in which said invention or . . . or patent directed thereto may be involved." *Amgen*, 2007 WL 1425854, at *1 (emphasis added).

Accordingly, Nippon Shinyaku's motion to compel Sarepta and UWA to make at least one of Dr. Sue Fletcher and Dr. Graham McClorey available for deposition is **DENIED**.

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This Memorandum Opinion and Order is preliminarily submitted under seal as a precaution because various portions of the underlying briefing and June 21, 2023 Hearing Transcript were marked highly confidential. Within three (3) business days of this Order, the parties shall jointly email the Special Master and advise of any proposed redactions.

IT IS SO ORDERED.

Dated: July 6, 2023

Monte T. Squire

Special Master Monté T. Squire